

## II. LISTING OF THE CLAIMS

Claim 1. (Previously presented) A solid controlled release oral dosage form, comprising a therapeutically effective amount of tramadol or a pharmaceutically acceptable salt thereof incorporated into a matrix, said dosage form providing a therapeutic effect for at least about 24 hours.

Claim 42. (Previously presented) The controlled release dosage form as claimed in claim 1, wherein said matrix is a controlled release matrix.

Claim 43. (Previously presented) The controlled release dosage form as claimed in claim 1, wherein said matrix is overcoated with a controlled release coating.

Claim 44. (Currently amended) The controlled release dosage form as claimed in claim 43 22, wherein said matrix is a normal release matrix.

Claim 45. (Currently amended) The controlled release dosage form as claimed in claim 43 22, wherein said matrix is a controlled release matrix.

Claim 46. (Previously presented) The controlled release dosage form as claimed in claim 1, containing from about 50 to 800mg of tramadol or a pharmaceutically acceptable salt thereof, calculated as the hydrochloride salt.

Claim 47. (Previously presented) The controlled release dosage form as claimed in claim 1, having a dissolution rate in-vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 0 to about 50% tramadol released after 1 hour; from about 0 to about 75% tramadol released after 2 hours; from about 10 to about 95% tramadol released after 4 hours; from about 35 to about 100% after 8 hours; from about 55 to about 100% tramadol released after 12 hours; from about 70 to about 100% tramadol released after 16 hours; and greater than 90% tramadol released after 24 hours, by weight.

Claim 48. (Previously presented) The controlled release dosage form as claimed in claim 1, having a dissolution rate in-vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 0 to about 30% tramadol released after 1 hour; from about 0 to about 40% tramadol released after 2 hours; from about 3 to about 55% tramadol released after 4 hours; from about 10 to about 65% after 8 hours; from about 20 to about 75% tramadol released after 12 hours; from about 30 to about 88% tramadol released after 16 hours; from about 50 to about 100% tramadol released after 24 hours and greater than 80% tramadol released after 36 hours, by weight.

Claim 49. (Previously presented) The controlled release dosage form as claimed in claim 1, having a dissolution rate in-vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 15 to about 25% tramadol released after 1 hour; from about 25 to about 35% tramadol released after 2 hours; from about 30 to about 45% tramadol released after 4 hours; from about 40 to about 60% after 8 hours; from about 55 to about 70% tramadol released after 12 hours; and from about 60 to about 75% tramadol released after 16 hours, by weight.

Claim 50. (Previously presented) The dosage form according to claim 1, which provides a  $t_{\max}$  from about 3 to about 6 hours.

Claim 51. (Previously presented) The dosage form according to claim 1, which provides a  $W_{50}$  from about 10 to about 33 hours.

Claim 52. (Previously presented) A solid controlled release oral dosage form, comprising a therapeutically effective amount of tramadol or a pharmaceutically

acceptable salt thereof incorporated into a matrix, said dosage form providing a therapeutic effect for at least about 12 hours.

Claim 53. (Currently amended) The controlled release dosage form as claimed in claim ~~52~~ 34, wherein said matrix is a controlled release matrix.

Claim 54. (Currently amended) The controlled release dosage form as claimed in claim ~~52~~ 34, wherein said matrix is overcoated with a controlled release coating.

Claim 55. (Currently amended) The controlled release dosage form as claimed in claim ~~54~~ 33, wherein said matrix is a normal release matrix.

Claim 56. (Currently amended) The controlled release dosage form as claimed in claim ~~54~~ 33, wherein said matrix is a controlled release matrix.

Claim 57. (Currently amended) The controlled release dosage form as claimed in claim ~~34~~ 52, containing from about 50 to 400mg of tramadol or a pharmaceutically acceptable salt thereof, calculated as the hydrochloride salt.

Claim 58. (Currently amended) The controlled release dosage form as claimed in claim ~~34~~ 52, having a dissolution rate in vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 0 to about 50% tramadol released after 1 hour; from about 0 to about 75% tramadol released after 2 hours; from about 3 to about 95% tramadol released after 4 hours; from about 10 to about 100% after 8 hours; from about 20 to about 100% tramadol released after 12 hours; from about 30 to about 100% tramadol released after 16 hours; from about 50 to about 100% tramadol released after 24 hours; and greater than 80% tramadol released after 36 hours, by weight.

Claim 59. (Currently amended) The controlled release dosage form as claimed in claim ~~31~~ 52, having a dissolution rate in vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 20 to about 50% tramadol released after 1 hour; from about 40 to about 75% tramadol released after 2 hours; from about 60 to about 95% tramadol released after 4 hours; from about 80 to about 100% after 8 hours; and from about 90 to about 100% tramadol released after 12 hours, by weight.

Claim 60. (Currently amended) The controlled release dosage form as claimed in claim ~~31~~ 52, having a dissolution rate in vitro when measured using the Ph. Eur. Paddle Method at 100 rpm in 900 ml 0.1N hydrochloric acid at 37°C and using UV detection at 270 nm, from about 5 to about 50% tramadol released after 1 hour; from about 10 to about 75% tramadol released after 2 hours; from about 20 to about 95% tramadol released after 4 hours; from about 40 to about 100% after 8 hours; more than 50% tramadol released after 12 hours; more than 75% tramadol released after 18 hours; and more than 80% tramadol released after 24 hours, by weight.

Claim 61. (Currently amended) The dosage form according to claim ~~31~~ 52, which provides a  $t_{\max}$  from about 1.5 to about 8 hours.

Claim 62. (Currently amended) A dosage form according to claim ~~31~~ 52, which provides a  $W_{50}$  from about 7 to about 16 hours.